# Kaletra Still Shows No Benefit for COVID-19

The HIV protease inhibitor combination did not speed recovery or reduce the risk of death in a large study.

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The combination antiretroviral pill Kaletra (lopinavir/ritonavir), used to treat HIV, still does not appear to offer any benefit for people with moderate to severe COVID-19, according to newly published study findings.

Among hospitalized COVID-19 patients in the large RECOVERY trial, the duration of hospitalization, the proportion needing mechanical ventilators and the mortality rate were similar for people assigned to Kaletra and those who received standard care.

“The result from the RECOVERY trial is clear. When combined with findings from an earlier, smaller trial and with the World Health Organization interim results, this provides strong evidence that lopinavir-ritonavir is not an effective treatment for patients hospitalized with COVID-19,” one of the trial’s lead investigators, Peter Horby, MD, PhD, of the University of Oxford, said in a press release.

The idea of using Kaletra (also sold as Aluvia outside the United States) for COVID-19 grew out of experiences with the drug combo during the 2003 SARS outbreak, caused by a coronavirus related to SARS-CoV-2, the virus that causes COVID-19. Kaletra showed activity against the first SARS virus in laboratory studies and was linked to improvement in some patients. A recently published study found that a combination of Kaletra and interferon beta reduced mortality in people with MERS (Middle East Respiratory Syndrome), caused by another related coronavirus.

However, a small study of COVID-19 patients in China early in the pandemic, which enrolled 199 hospitalized people with reduced oxygen levels, found that Kaletra was no more effective than standard supportive care. Yet the study offered a hint that the combination pill might help people who are treated early.

Now, a much larger randomized, controlled trial offers more definitive evidence that Kaletra is not an effective treatment option for the new disease.

RECOVERY has enrolled some 12,000 COVID-19 patients at 176 hospitals in the United Kingdom. The ongoing study is comparing multiple treatments and is evolving as new therapies become

available. In addition to Kaletra, the study is testing the steroid dexamethasone (which was found to reduce the risk of death for people with severe COVID-19), azithromycin (a commonly used antibiotic), the anti-inflammatory drug Actemra (tocilizumab), convalescent plasma (blood plasma from recovered COVID-19 patients) and Regeneron's monoclonal antibody cocktail. Hydroxychloroquine, an old drug famously touted by President Trump, was discontinued after it showed no benefit.

Starting in March, a total of 1,616 RECOVERY participants were randomly assigned to receive Kaletra tablets twice daily for 10 days, while 3,424 were assigned to usual care.

The RECOVERY investigators released preliminary results in late June, which led to the discontinuation of the Kaletra arm of the study. The full findings were published this month in The Lancet. Like RECOVERY, the World Health Organization's large SOLIDARITY trial also halted its Kaletra arm after disappointing findings.

In RECOVERY, Kaletra did not reduce the risk of death within 28 days: Mortality rates were 23% in the Kaletra group versus 22% in the usual care group. The duration of hospitalization was also similar. In both groups, the median stay was 11 days; 69% of patients in the Kaletra group and 70% in the usual care group were discharged within 28 days. What's more, 10% of people assigned to Kaletra needed to be put on a ventilator, compared with 9% of those receiving usual care.

The researchers noted that these results were consistent across patient subgroups, and no evidence of benefit from Kaletra was observed in any of the groups according to age, sex, race/ethnicity or duration of illness.

Treatment was safe and generally well tolerated. No differences were noted between the Kaletra and usual care groups with regard to the frequency of bradycardia, a heart rhythm abnormality previously seen as a side effect of Kaletra. One patient developed a severe ALT liver enzyme elevation but recovered after stopping treatment.

Some clinical care guidelines have recommended Kaletra for COVID-19 treatment, but, based on these findings, such guidelines should be updated, said another RECOVERY lead investigator, Martin Landray, MBChB, PhD, of the University of Oxford.

"Treatment of COVID-19 with the drug combination lopinavir-ritonavir has been recommended in many countries," Landray said in the press release. "However, results from this trial show that it is not an effective treatment for patients admitted to [the] hospital with COVID-19."

The U.S. National Institute of Health's COVID-19 treatment guidelines have already removed Kaletra as a recommended option.

This also means there is no reason for HIV-positive people who are currently taking other antiretrovirals to switch to Kaletra in an effort to prevent or treat COVID-19.

Nonetheless, antivirals like Kaletra could be worth testing as an early treatment for mild COVID-19 or even as a post-exposure prevention option, Bin Cao, MD, of the National Clinical Research Center for Respiratory Diseases in Beijing—the lead author of the earlier Chinese study—and Frederick Hayden, MD, of the University of Virginia School of Medicine in Charlottesville, suggested in an editorial accompanying the Lancet report.

“Given the efficient replication of SARS-CoV-2 shortly after infection and the association between mortality and viral RNA loads at diagnosis, it is possible that early use of sufficiently potent antiviral drugs would be an important determining factor in clinical outcomes, although few early intervention trials have been completed,” they wrote.

Click here to read the study.

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